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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/384,248	02/06/1995	MARC ALIZON	3495.0008-08	9162
22852	7590	12/12/2007		
FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP 901 NEW YORK AVENUE, NW WASHINGTON, DC 20001-4413			EXAMINER PARKIN, JEFFREY S	
			ART UNIT 1648	PAPER NUMBER
			MAIL DATE 12/12/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

**Application No.**

08/384,248

**Applicant(s)**

ALIZON ET AL.

**Examiner**

Jeffrey S. Parkin, Ph.D.

**Art Unit**

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 03 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 11 November 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 37-39 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 37-39 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

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Docket No.: 3495.0008-08  
Filing Date: 02/06/1995

### **Detailed Office Action**

#### ***Status of the Claims***

Acknowledgement is hereby made of receipt and entry of the amendment after Board decision received 11 September, 2006. In a previous interview with applicants' representative conducted on 05 April, 2007, an attempt was made to find allowable subject matter in this application. Applicants were reminded that the general policy of the Office is not to permit the applicant to shift to claiming another invention after an election is once made and action given on the elected subject matter, particularly at this late stage of prosecution. See M.P.E.P. § 819. However, it appeared that the examiner and attorney were able to identify allowable subject matter. As a courtesy to applicants, the examiner agreed to entertain an allowable submission. Claims 37-39 were submitted in the aforementioned response. Claims 37-39 are the only pending claims.

#### ***35 U.S.C. § 120 Benefit***

Acknowledgement is hereby made of applicants priority claims under 35 U.S.C. § 120. Perusal of the applications relied upon demonstrates that U.S. Serial Nos. 06/558,109, filed 05 December, 1983, and 06/706,562, filed 28 February, 1985, fail to provide adequate support for the claimed invention. Neither of these applications discloses what could reasonably be termed an "endogenous" reverse transcriptase assay. Accordingly, for the purposes of applying prior art, this application has been afforded an effective filing date of 30 August, 1985.

#### ***35 U.S.C. § 112, Second Paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims

particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 37-39 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Two separate requirements are set forth under this statute: (1) the claims must set forth the subject matter that applicants regard as their invention; and (2) the claims must particularly point out and distinctly define the metes and bounds of the subject matter that will be protected by the patent grant. The claims reference an "endogenous reverse transcriptase" assay yet fail to provide the requisite steps required to perform such an assay. An endogenous RT assay uses endogenous viral RNA (not oligo dT) as the template for reverse transcription (Goncalves et al., 1996). Virions are permeabilized with detergent, incubated with dNTPs, a divalent cation, buffer, and radiolabeled dNTP. The claimed assay describes virion purification, lysing said virions with detergent to produce a lysate, performing reverse transcription, and detecting the reaction products. It is not readily manifest if step (b) is a virion permeabilization or lysis step. An endogenous assay would simply permeabilize the virions whereas an exogenous assay would lyse them. Moreover, the exogenous assay would also require the addition of an oligo dT primer, which is currently missing from the claims. Thus, the metes and bounds of the patent protection desired can not be ascertained.

**35 U.S.C. § 102**

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 37-39 are rejected under 35 U.S.C. § 102(b) as being clearly anticipated by *Rey et al.* (1984). *Rey* and associates describe an endogenous reverse transcriptase (RT) assay employing the lymphadenopathy-associated viral (LAV) RT. This teaching appears to meet all of the claimed limitations.

**35 U.S.C. § 112, First Paragraph**

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

*New Matter*

Claims 37-39 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. *In re Rasmussen*, 650 F.2d 1212, 211 U.S.P.Q. 323 (C.C.P.A. 1981). The claimed invention is directed to an "**endogenous**" *in vitro* HIV-1 RT assay. As set forth *supra*, an endogenous RT assay uses endogenous viral RNA (not oligo dT) as the template for reverse transcription (Goncalves et al., 1996). Virions are permeabilized with detergent, incubated with dNTPs, a divalent cation, buffer, and radiolabeled dNTP. The disclosure

fails to describe any endogenous RT assays. The only assays provided in the disclosure actually appear to be exogenous assays (although at one point they are referenced as a "virus-associated detergent activated endogenous reaction"). All of the disclosed assays and examples in the specification employ an oligo dT template which is required for exogenous RT assays (i.e., see p. 6, First-strand cDNA synthesis). Accordingly, since an endogenous assay is not clearly set forth in the specification, the skilled artisan would reasonably conclude that applicants were not in possession of the claimed invention at the time of filing.

### ***Correspondence***

Any inquiry concerning this communication should be directed to Jeffrey S. Parkin, Ph.D., whose telephone number is (571) 272-0908. The examiner can normally be reached Monday through Thursday from 10:30 AM to 9:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Bruce R. Campell, Ph.D., can be reached at (571) 272-0974. Direct general status inquiries to the Technology Center 1600 receptionist at (571) 272-1600. Informal communications may be submitted to the Examiner's RightFAX account at (571) 273-0908.

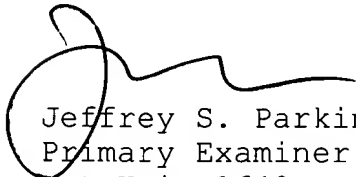
Applicants are reminded that the United States Patent and Trademark Office (Office) requires most patent related correspondence to be: a) faxed to the Central FAX number (571-273-8300) (updated as of July 15, 2005), b) hand carried or delivered to the Customer Service Window (now located at the Randolph Building, 401 Dulany Street, Alexandria, VA 22314), c) mailed to the mailing address set forth in 37 C.F.R. § 1.1 (e.g., P.O. Box 1450, Alexandria, VA 22313-1450), or d) transmitted to the Office using the Office's Electronic Filing System. This notice replaces all prior Office notices specifying a specific fax number or hand carry address for certain patent related correspondence. For further information refer to the Updated Notice of Centralized Delivery and Facsimile Transmission Policy for Patent Related Correspondence, and Exceptions Thereto, 1292 Off. Gaz. Pat. Office 186 (March 29, 2005).

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be

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obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Respectfully,

A handwritten signature in black ink, consisting of a large, stylized 'J' followed by a series of loops and a horizontal line extending to the right.

Jeffrey S. Parkin, Ph.D.  
Primary Examiner  
Art Unit 1648

04 December, 2007